

In the Specification:

On page 4 under “Detailed Description of the Invention” through page 13, please replace the following paragraphs:

--Detailed Description of the Invention:

Referring now to Figure 1, there is shown a perspective view of the access port according to one embodiment of the present invention in which the hollow body 9 of fluid-impervious material includes a central bore 15 and a generally toroidally-shaped balloon 11 disposed about the outer periphery of the body 9 near the distal end 13 thereof. The interior diameter of the central bore 15 through the hollow body 9 is sized to accommodate the largest diameter of endoscopic instrument therein and may be about 0.6” at the distal end 13, and may flair out to a wider diameter of about 0.9” at the proximal end 18. A fluid or air passage 17 along an outer wall of the body 9 connects to an external fluid-tight coupling or fitting 20 for coupling to a source of gas under pressure, such as a syringe, in order to selectively inflate the balloon 11 within the confines of an initial cutaneous incision near a saphenous vein that is to be harvested. Inflating the balloon 11 with fluid under pressure, as shown in Figure 2, seals and mechanically anchors the body 9 within an incision to serve as the access port for endoscopic

instruments thereafter inserted through the central bore 15 of the hollow body 9 into the incision.

Referring now to Figure 3, there is shown a perspective view of the body 9 as a molded component formed, for example, of bioinert material such as polycarbonate. Specifically, the body 9 includes an integral air passage 17 communicating with the gas fitting 20 and the aperture 22 (within the volume confined by the balloon 11, not shown). This integral air passage thus facilitate selective inflation of the balloon 11 via a pressure fitting 20. Alternatively, the fitting 20 may include a one-way valve to retain inflation of the balloon until such valve is selectively released. The balloon 11 is attached to the body 9 within the circumferential groove, or grooves, 24 near the outer perimeter of the distal end 13, and is also attached to the circumferential groove 26 about the outer perimeter of the body 9 at a location thereon intermediate the distal end 13 and proximal end 18. The integral air passage 17 extends the outer dimension of the body 9 between the pressure fitting 20 and the aperture 22, so groove 26 may be elliptical in the plane normal to the axis of the central bore 15. A balloon 11 thus attached to the body 9, as described above, may inflate in substantially toroidal configuration, as illustrated in Figure 2, with an elliptical shape

disposed within groove 26 and a substantially circular shape disposed within groove 24.

At the proximal end 18 of the body 9, the central bore 15 flairs out to a larger diameter over a short transition section 23 that provides an internal wall which tapers between the larger and smaller diameter segments of the central bore 15. The outer perimeter of the proximal end 18 of the body 9 includes a recessed groove 30 that accommodates gas-tight attachment of a resilient seal, later described herein. The expanded diameter of the central bore 15 near the proximal end 18 of the body 9 accommodates a wide range of angulation of an endoscopic instrument within the central bore 15 without interference from the side walls of the internal bore. Also, as shown in the proximal end view of Figure 4, an insufflation gas inlet 25 is formed on the transition section 23, with an internal aperture 28 positioned in the tapering internal wall of the transition section 23. This assures that insufflating gas or other fluid supplied through the conduit 19 and the aperture 28 will not be blocked or restricted by an endoscopic instrument of largest diameter inserted within the central bore 15. In another embodiment of the present invention, the conduit 19 for insufflating gas or other fluid under pressure may be normally sealed off, for example, via a resiliently-biased disk against a downstream valve seat, with a control arm 33 rigidly attached centrally on

the disk and protruding through the aperture 28 into the central bore 15 to open the valve in response to an endoscopic instrument inserted in central bore 15 to displace the control arm 33. Molding of the body 9 with an air passage between the ~~pressure~~ fitting 20 and the aperture 22 (for inflating the balloon 11) is greatly facilitated by a pin-like mandrel disposed away from, but aligned with, the central bore 15 and emanating through the internal tapered wall of the transition section 23. Such pin-like mandrel intersects with another mandrel that forms the internal bore through the ~~pressure~~ fitting 20 to provide the integrally-molded air passage 17 between fitting 20 and aperture 22, with a remnant aperture 32 remaining in the internal tapered wall where the pin-like molding mandrel was withdrawn. This aperture 32 may be permanently plugged with a drop of glue or sealant, or the like, to provide a gas-tight air passage between fitting 20 and the aperture 22. Alternatively, a tube as an insert may be molded into the body 9 to form the air passage between fitting 20 and aperture 22, without an aperture 32 formed during such molding procedure.

In another embodiment, the body 9 and ~~the~~ a sliding seal 21 may be integrally formed as a single molding of a bioinert material such as silicone rubber. In such embodiment, the more rigid section of the body 9 includes thicker walls and the more flexible section of the seal 21 includes thinner

walls, with other components, features and configuration (except a groove 30) formed as previously described herein.

Referring now to Figure 5, there is shown a sectional view of a generally round ~~sliding-seal component~~ 21 for gas-tight attachment to the generally cylindrical proximal end 18 of the body 9. The seal 21 is formed of resilient, flexible polymeric material to include a central aperture 35. The aperture 35 overlays and aligns with the central bore 15 at the proximal end of the hollow body. The aperture 35 has a smaller diameter than the largest endoscopic instrument to be inserted through the hollow body 9. A sliding gas-tight seal is thus formed about the outer generally cylindrical surface of an endoscopic instrument during insertion thereof through the hollow body 9. The outer perimeter of the ~~gas seal component~~ 21 is configured to overlap the proximal end 18 of the body 9 and resiliently snap into groove 30 for gas-tight and mechanically-secure attachment to the body 9. Specifically, the distal end 34 is configured to insert within the internal walls of the proximal end 18 of the body 9, and includes an integrally-formed raised or protruding ring 36 on such outer diameter to provide a deformable gas-tight seal between the ~~gas seal component~~ 21 and the internal walls of the body 9. In addition, the overlapping flange 38 at the proximal end of the ~~gas seal component~~ 21 includes a descending and inwardly extending portion 37 that

is integrally formed on the ~~gas seal component~~ 21 to engage within the groove 30 in the outer perimeter near the proximal end of the body 9. In addition, the inwardly extending portion includes an integrally-formed inwardly extending or intruding ring 39 that provides a deformable gas seal within the groove 30 in body 9. The ~~gas-sealing component~~ seal 21 thus configured forms gas-tight seals about the proximal end 18 of the body 9, and forms a sliding gas-tight seal about an endoscopic instrument inserted through the aperture 35. The ~~entry port~~ aperture 28 into the hollow body 9 is positioned interior of ~~sliding~~ seal 21 for supplying gas under pressure via ~~gas line~~ conduit 19 to an anatomical space into which the access port is inserted. Thus, with the body 9 sealed and anchored within an incision by the inflated balloon 11, and with an endoscopic instrument inserted through the ~~sliding~~ seal 21 and hollow body 9, an anatomical space of confined volume is formed about a saphenous vein to be harvested which can be insufflated with gas under pressure supplied to the confined volume through the ~~fluid~~ conduit 19 and aperture ~~entry port~~ 28. As the endoscopic instrument is removed from the access port, the fluid seal around the endoscope is disabled, and air or other fluid under pressure within the confined volume about the saphenous vein equalizes rapidly toward ambient pressure. Only after an endoscopic instrument is again inserted within the central bore of the hollow

body 9 is the fluid seal re-formed at aperture 35, and the confined volume about the saphenous vein re-insufflated with gas or other fluid under pressure that may be continuously supplied via the ~~gas entry port~~ aperture 28.

For operation with an endoscopic instrument of smaller exterior diameter than would form a seal within aperture 35, sliding auxiliary gas seal 41 may be formed in the configuration as illustrated in Figure 6 for insertion into the aperture 35 of seal 21. The auxiliary seal 41 is substantially circularly toroidal with an internal bore 43 of larger diameter than the diameter of the sealing aperture 45 at the proximal end 47. A tapered and outwardly extending hook-like ring 51 is integrally formed on the distal end 49 of the auxiliary seal 41 at a distance from the proximal end 47 suitable for engaging the inner surface 54 behind the diaphragm member 56. Alternatively, the ring 51 may be integrally formed on the distal end 49 of the auxiliary seal 41 at a distance from the proximal end 47 suitable for engaging the distal end 34 of the seal 21. The outer diameter 53 is disposed to fit within the inner diameter of seal 21 at the distal end thereof. In this way, the auxiliary seal 41 may form a gas-tight and mechanically-stable auxiliary seal about endoscopic instruments of smaller diameter suitable for forming a sliding seal within aperture 45. The toroidally-shaped ~~seals~~ seal

21, and auxiliary seal 41 may be formed of a flexible, resilient material such as polyurethane, silicone, latex rubber, Nitrile, or the like, to exhibit resilient flexibility upon installation of seal 21 over the proximal end 18 of the body 9, and upon optional installation of the auxiliary seal 41 within the aperture 35 of seal 21. A seal 21 formed and assembled in this manner on the body 9 with optional auxiliary seal 41 inserted in seal 21, significantly reduces the length and mass and associated cost of an access port suitable for accommodating large-diameter and small-diameter endoscopic instruments while also supporting insufflation of a surgical site, such as along a saphenous vein, of relatively small confined volume. In addition, the short length of body 9 greatly extends the range of angulation of an endoscopic instrument within the central bore 15 without adversely altering the position of the body 9 sealed within an incision. And, the inner walls of the resilient seal 21 and auxiliary seal 41 serve as bumpers to limit angular and lateral movement of an endoscopic instrument and prevent distortion of the associated aperture in response to excessive angular movement. The ~~balloon inflation port~~ fitting or coupling 20 and the conduit 19 and insufflation gas ~~port 19~~, inlet 25 may also be oriented in substantial axial alignment, rather than in lateral alignment, with the central bore 15 to increase the range of angular orientations of the body 9 within an incision. Axial configuration of



the gas ports in another embodiment of the present invention facilitates reduced size of the body and insertion thereof into an incision with the seal 21 oriented distally and the balloon 11 oriented proximally. And, an eccentric mounting of the balloon on the body at a location thereon intermediate the distal and proximate ends promotes wider angles of orientation of the central bore relative to an incision formed above a saphenous vein to be harvested. The body with attached balloon and one or more resilient seals having apertures of various diameters, and including an auxiliary seal 41 for fluid-tight insertion into the aperture of a ~~resilient~~ seal 21 that attaches to the proximal end of the body 9, may all be assembled in pre-sterilized condition within a hermetically-sealed conventional tray pack or pillow pack, as illustrated in Figure 7, to facilitate forming an insufflation access port with sliding seals about endoscopic instruments of various exterior dimensions.--